



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/718,754	11/22/2000	Kathryn K. Lappegard	1189	3443

27310 7590 07/30/2002

PIONEER HI-BRED INTERNATIONAL INC.
7100 N.W. 62ND AVENUE
P.O. BOX 1000
JOHNSTON, IA 50131

EXAMINER

BAUM, STUART F

ART UNIT PAPER NUMBER

1638

DATE MAILED: 07/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/718,754	LAPPEGARD ET AL.	
	Examiner	Art Unit	
	Stuart Baum	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 6, 11, 17, 21, and 40-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 11, 17, 21, 40-43 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

The amendment filed May 8, 2002, paper no. 9, has been entered.

Claims 3-5, 7-10, 12-16, 18-20, and 22-39 have been cancelled.

Claims 1, 2, 6, 11, 17, and 21 have been newly amended.

Claims 40-43 have been newly added.

Claims 1, 2, 6, 11, 17, 21, and 40-43 are pending.

The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action

Claims 1-2, 11, 17, 21, 40, and 42-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed January 30, 2002.

Applicants arguments filed May 8, 2002 have been fully considered but they are not persuasive.

The Applicant contends that the "application discloses structure via DNA sequence (SEQ ID NO:1)" and that the function is correlated with this structure. The Applicant continues by stating "physical and chemical properties associated with the claimed sequences are defined by hybridization conditions". Applicant interprets *Eli Lilly* to be pertinent to the biological properties of claimed sequences whereas their limitations focus on the structural properties as defined by percent identity and hybridization fidelity.

The Examiner disagrees with the Applicant that hybridization conditions define the chemical and physical properties associated with the claimed sequence. Hybridization

conditions do not tell you anything about the properties of your sequence they only indicate which sequences have a certain degree of homology based on the hybridization conditions. Only by isolating other maize Jip1 promoters from other species and aligning the respective sequences and looking for regions that are conserved between the aligned sequences will one begin to understand the physical and chemical properties associated with their respective sequence. Describing a genus facilitates the understanding of the physical and chemical properties associated with their particular species.

Claims 1-2, 11, 12, 17, 21, 40, and 42-43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to the 1247 bp's 5' of an isolated maize Jip1 coding region (SEQ ID NO:1) operably linked to a desired gene and transformed into a maize plant, to obtain expression in 15-40 days-after-pollination (DAP) embryos with some weaker expression in the endosperm and pericarp (referred to further as seed-preferred expression) does not reasonably provide enablement for claims broadly drawn to a sequence that hybridizes to SEQ ID NO:1 under highly stringent conditions, or a sequence having at least 65% sequence identity to SEQ ID NO:1 drawn to plant transformation with the exemplified or non-exemplified promoter regions for obtaining expression in 15-40 DAP embryos with some weaker expression in the endosperm and pericarp. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record set forth in the office action mailed January 30, 2002.

The Applicant contends that the specification provides sufficient guidance for one skilled in the art to evaluate sequences that would be encompassed as hybridizing to SEQ ID NO:1 under stringent conditions, or sequences having at least 65% identity to SEQ ID NO:1 without

causing undue experimentation. The Applicants also acknowledge the references cited by the Examiner (i.e. Izawa et al, Hao et al, Busch et al and Lohmann et al) but again contend that it would not require undue experimentation to identify those sequences that function as a Jip1 promoter. The Applicants parse the Examiner's cited references trying to demonstrate that the cited references are not relevant to their invention. The Applicant contends that small additions, deletions, and/or substitutions within a Jip1 promoter may destroy the promoter's activity but it is a matter of routine experimentation to create or isolate alternative functional Jip1 promoters. Applicant also states that the bZip transcription factors referred to by Izawa et al are not relevant to the present application. The Applicant addresses *In re Wands* and recites from that court decision that a "considerable amount of experimentation is permissible if it is merely routine". The Applicant concludes by stating that screening libraries containing a few positive promoter fragments would not be considered undue experimentation.

The Examiner disagrees with the Applicant in what constitutes an undue experimentation. Isolating a promoter fragment from a library is just the first step in a long arduous process. Not only do clones have to be isolated, but they then have to be subcloned, sequenced, transformed into plants and sectioned. For each putative promoter fragment, 15-20 individual transformants have to be analyzed via sectioning and or GUS analysis. The claims are written so broadly, that sequences with 65% identity or those sequences which hybridize using 2X SSC at 65C for 30 minutes (as specified in the specification) would generate hundreds if not thousands of sequences that would have to be tested to find ones that give the correct spatial and temporal expression. The references cited by the Examiner are given as examples to demonstrate that small additions, deletions, and /or substitutions may destroy the promoter's activity. The field of molecular developmental biology is very new and not all promoter or transcription factors have been

analyzed. So even if the examples given by the Examiner are dealing with promoters or as the Applicant has pointed out, with intronic regions, the mechanisms are pertinent to the present invention.

Claim 21 and claims 40-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as stated in the last office action.

Claims 21, and 40-43 are indefinite as the open language of the claim is confusing and implies that there is another piece of DNA with regulating characteristics that is operably linked to “a second nucleotide sequence selected from the group consisting of”. Applicants are requested to amend the language of the claim to read on the elected regulatory element operably linked to a specified DNA sequence.

The Applicant amended claim 21 to recite “wherein the regulatory element comprises a second nucleotide sequence selected from the group consisting of: ...SEQ ID NO:1.....sequences having at least 65% identity to SEQ ID NO:1....sequences that hybridize to SEQ ID NO:1...and sequences natively associated with DNA coding for maize Jip 1 (jasmonate-induced protein).” This amendment is not found persuasive and the wording of the newly added claims 40-43 is indefinite because Applicant hasn’t stated what constitutes the first regulatory element. What type of promoter element is the Applicant referring to when they infer its existence by the presence of a second regulatory element?

The rejection of claims 1-3 under 35 U.S.C. 112, second paragraph is withdrawn based on the Applicants amendment.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-3014 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the legal analyst, Kim Davis, whose telephone number is (703) 305-3015. Stuart Baum Ph.D.

July 24, 2002


ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1800